

REMARKS

With this response, Claims 1, 6, and 23 have been amended, Claims 2-5 have been canceled without prejudice or disclaimer, and Claims 24-30 have been added. As such, Claims 1, 6-9, 11-13, 18-19, and 22-30 are pending. Support for the present amendment may be found in the original claims and specification, e.g., at Para [0016], [0047], claims 5 and 6, 8-13, 18-19, etc. No new matter enters by way of the present amendment. As such, entry of the amendment and reconsideration of the application as amended is respectfully requested.

I. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 11-13, 18, 19 and 22 stand rejected under 35 U.S.C. §112, Second Paragraph, as allegedly being indefinite. Applicants respectfully traverse for at least the reasons which follow.

In one aspect, the Examiner objects to the claims due to the recitation of the phrase “hydrophobic and/or lipophilic”. While acknowledging that the term “hydrophobic” is described with sufficient clarity to particularly point out and distinctly claim the subject matter Applicants regard as the invention, the Examination considers the term “lipophilic” indefinite. While Applicants do not agree with the Examiner’s characterization (noting that the Examiner has pointed to a definition provided in the specification and believe such definition provides a reasonable degree of precision and particularity to the scope of the claims), the claims have been amended without prejudice or disclaimer to specifically recite particular photosensitizer compositions. As such, it is believed that this rejection is now moot. As such, withdrawal of this rejection is respectfully requested.

The Examiner also objects to the claims due to the recitation of “analogs” of 5-aminolevulinic acid. Again, while not agreeing with this rejection, the claims have been amended without prejudice or disclaimer to specifically recite particular photosensitizer compositions. As such, it is believed that this rejection is now moot. As such, withdrawal of this rejection is respectfully requested.

II. Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-9, 11-13, 18, 19 and 22 stand rejected under 35 U.S.C. § 112, First Paragraph, as allegedly failing to comply with the written description requirement for allegedly containing new matter. While not agreeing with the rejection, solely to facilitate prosecution, Applicants

have amended the claims to positively recited particular photosensitizer compositions and particular sebaceous gland disorders, without prejudice or disclaimer to the underlying subject matter. As such, this rejection is now moot.

III. Rejections under 35 U.S.C. § 103

Claims 1-9, 11-13, 18, 19, 22 and 23 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over QLT Inc. WO 03/039597 A1 (hereinafter “QLT”) in view of Kalka et al J Am Acad Dermatol Mar 2000 (hereinafter “Kalka”) as allegedly being obvious. Applicants respectfully traverse for at least the reasons which follow.

Again, the present independent claims are directed to methods for treating recited hyperactive sebaceous gland disorders in a subject in need thereof, the method comprising topically applying a photosensitizer composition to skin tissue of said subject exhibiting symptoms of a hyperactive sebaceous gland disorder and exposing the tissues of said subject to light energy. As acknowledged by the Examiner, QLT is completely silent with regard to methods for treating hyperactive sebaceous gland disorders, but rather teaches the treatment of other skin conditions and disorders. To remedy this deficiency, the Examiner points to alleged teachings of Kalka and asserts that it would have been obvious to those skilled in the art to employ methods of treating hyperactive sebaceous gland disorders “motivated by the teaching of Kalka and QLT Inc. that teach both psoriasis and seborrhea are well known to be treated with porphyrins and light energy.” Office Action issued June 10, 2011 at page 13. Again, Applicants respectfully traverse.

As discussed previously, it is submitted that Kalka does not in fact teach the treatment of the claimed hyperactive sebaceous gland disorders by topically applying a photosensitizer composition to skin tissue of a subject in need thereof and exposing the tissue of the subject to light energy, as required by the claims. As discussed, the disclosure of Kalka does not reference the topical application of a photosensitizer composition to skin tissue of a subject exhibiting symptoms of the claimed hyperactive sebaceous gland disorders. Rather, it merely references the destruction of lipophilic propionibacteria (i.e., a cause of acne) for management of acne vulgaris via use of blue light, and a resultant reduction in both acne and seborrhea. Kalka then suggests the possible value of PDT for benign inflammatory skin diseases and suggests further

exploration. Contrary to suggestions in the Office Action, Kalka does not in fact disclose the treatment of seborrhea by porphyrins and illumination with blue light.

For clarity, Applicants note that nowhere in the previous response did Applicants state that “Kalka teaches the destruction of lipophilic propionibacteria with **porphyrins** for management of acne vulgaris via use of blue light”, as alleged in the Office Action. See *Office Action* issued June 10, 2011 at page 10. In this regard, Kalka states “[t]he production of porphyrins by lipophilic propionibacteria has been utilized for photodynamic destruction of these micro-organisms for the management of acne vulgaris.” Kalka at page 403. However, Applicants did not state, nor does Kalka disclose, the destruction of lipophilic propionibacteria by topical application of porphyrins. Rather, Kalka appears to be referring to the native production of porphyrins by lipophilic propionibacteria *in vivo*, and the utilization of production of such for destruction of the micro-organisms.

At a minimum, in order to arrive at the presently claimed invention, one of skill would need to modify the teachings of QLT and Kalka so as to specifically provide a method with an intent to treat the claimed hyperactive sebaceous gland disorders, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. Again, the present claims require such a method, including topical application of a photosensitizer composition to skin tissue of a subject.

In accordance with proper claim interpretation, the present claims require a method with an intent to treat the recited hyperactive sebaceous gland disorders, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. QLT makes no suggestion of the specifically claimed methods. The mere disclosure in Kalka of destruction of lipophilic propionibacteria by produced porphyrins for management of acne vulgaris, the passing reference to reduction in both acne and seborrhea, and the express suggestion of possible value of PDT for benign inflammatory skin diseases and of further exploration is just that --- an invitation for further experimentation with no reasonable expectation of success concerning the specific intent of the presently claimed invention.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. There must also be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Moreover, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning **with some rational underpinning** to support the legal conclusion of obviousness.” *KSR Int’l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added).

As mentioned above, nothing in QLT or Kalka teaches or suggests a method with an intent to treat the recited hyperactive sebaceous gland disorders, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. Absent a suggestion of such a method, one of skill in the art would simply find no motivation to perform a method as recited in the present claims for the specific intended purpose of treating hyperactive sebaceous gland disorders, by topically applying a photosensitizer composition to a subject in need thereof. Further, there is no motivation to specifically modify the teachings of QLT, based on the teachings of Kalka so as to arrive at the specifically claimed methods with any reasonable expectation of success.

For at least these reasons, one of skill in the art would not look to modify the teachings of QLT alone or in view of Kalka so as to arrive at the presently claimed invention. Withdrawal of this rejection is therefore respectfully requested. The dependent claims are believed to be patentable for at least the reasons discussed above. In addition, each of the claims further recites specific parameters with regard to the treatment regimen and composition and are separately patentable for at least these reasons.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (303) 863-2303 should any additional information be necessary for allowance.

Respectfully submitted,

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